

VCU 02-14

**AMENDMENT WITH RCE**

02940323aa

Amendment dated 08/21/2008

Reply to office action mailed 03/21/2008

**REMARKS**

Claims 1-14 are currently pending in the application. By this amendment, claims 1 and 8 are amended for the Examiner's consideration. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

The Examiner's consideration in a telephone interview conducted on June 3, 2008, is acknowledged with appreciation. The Yost and Henriquez references were discussed. The applicant argued that the addition of Henriquez would make Yost inoperable because Henriquez used the eye as a window into the brain, just as the present invention, whereas Yost's measurement of skull expansion required a distance measurement between two points connected to the skull on opposite sides of the skull. The applicant argued that one skilled in the art would understand the differing methodologies of Yost (measuring skull expansion) and Henriquez (detecting acoustic signals indicative of an aneurism), and would not put Henriquez together with Yost.

The Examiner responded that Henriquez provided goggles over the eyes, and the goggles were in contact with the skull. The applicant pointed out that the direct contact between the goggles and the skull had nothing logically to do with the acoustic signal detection described in Henriquez, and could only be found relevant in hindsight. Further, the applicant questioned whether both aspects of the Examiner's argument could be advanced at the same time, that is, having both the Henriquez use of the eye as a "window" to the brain, as in the present invention, and also using the goggles in contact with the skull, in effect arguing that the signals in Henriquez were sensed at the skull in order to provide a motivation to link to Yost.

However, the Examiner noted that the argument regarding use of the eye as a "window" to the brain better applied to a method claim than the apparatus of claim 1. The Examiner also pointed out that Yost would be operable if one side of the

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headgear were placed over an eye, in contact with the bone around the eye socket. It was pointed out that this configuration would meet the language “adapted to an eyeball,” and suggested that if the language were changed to “in contact with an eyeball” that might overcome the rejection, but might be narrower than the inventor wanted.

In conclusion the Examiner suggested that language be added to the claim limitation at lines 3-4 in claim 1 to clarify that the measurement was not being made at the skull, and that the language of Alternate 1 (claim 1, lines 9-11) in the interview Agenda be added. It would then be considered whether the distinguishing claim amendments could be accepted without a further search, or whether an Advisory Action would make an RCE necessary.

In view of the Advisory Action mailed July 31, 2008, applicant acknowledges that the Examiner has concluded that a further search will be necessary. It is respectfully and specifically requested that the Examiner contact the undersigned for a telephone interview in the event that the Examiner should find that the foregoing amendments do not place the application in condition for allowance, in order to discuss any further changes deemed necessary.

In response to the interview of June 3, 2008, the claims have been amended to add language that clarifies the distinction argued by the applicant regarding the acoustic eye patch, namely, that the sensor measurements are not taken at the skull, and in particular that the sensor not touch the skull and, therefore, not come in contact with the eye socket. The importance of this limitation is described at page 10, lines 1-5. If the sensor touches the skull the resulting spectrum is much like that recorded from the skull. Thus the present invention is inoperable if the sensors touch the skull. Consequently, the language “without the sensors coming into contact with a skull portion of a socket for said eyeball” is added.

It is believed that this amendment overcomes the grounds of rejection based on Yost, because for Yost to be operable the sensors must be in contact with the skull.

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Further, in apparatus claim 1, the limitation from proposed Alternate 1 regarding measurement and analysis of acoustic damping has been added, as described at page 7, lines 4-6, page 8, lines 1-10, and page 9, lines 8-19 and 26-30. It should be noted that this further wherein clause, which clarifies the “window to the brain” for apparatus claim 1, has not been applied to independent method claim 8. It is believed that the foregoing amendment regarding lack of contact between the sensor and skull is sufficient, at least with regard to method claim 8. It will be observed that the invention can be implemented at a low frequency range as described in claim 14 and page 15, lines 8-21, by detection of retinal artery pulsations rather than damping.

In the Office Action, written in advance of the interview, the Examiner maintains rejection of claims 1, 3, 5, 6, 8, 12 and 13 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0191411 to Yost et al. (“Yost”) in view of U.S. Patent No. 5,129,403 to Henriquez et al. (“Henriquez”). The Examiner repeated the arguments present in the earlier office action, and added a response. The substance of the response was a) that the former claim language does not track the distinction made, namely, the “invention uses the acoustic signal as an actual intra cranial pressure measurement”, and b) the Yost reference meets the limitations of the claims because “the skull is a part of the brain.”

The latter assertion is plainly incorrect. It may be said that the “brain” and the “skull” are both part of the “head,” and that the brain is contained in (and protected by) the skull, but clearly the brain and the skull are separate and different structures.

However, the argument is now moot in view of the above amendment which makes explicit that the sensors in the present invention as claimed have no contact with the skull.

Yost discloses a methodology for determining absolute intracranial pressure (ICP) using reference measurements of skull expansion. The first reference measurement is of the patient’s blood pressure  $P_{vb}$  (venous bed pressure) when skull expansion is approximately zero (abstract; ¶0021). It is known in the art that ICP is

equal to  $P_{vb}$  at zero skull expansion (§0031). Zero skull expansion is indicated when there is a zero phase difference between an acoustic transmitter (e.g. transducer 30, mounted to pressure pad 26) and an acoustic receiver (e.g. transducer 31, mounted to pressure page 28) of an acoustic signal applied to the skull by the acoustic transmitter (§0029). Skull expansion is monitored by using the acoustic signal to measure the physical distance between any two measurement points (e.g. transducers 30 and 31)(§0033-0036). With this monitor in place, a second reference measurement is made by inducing a known change in ICP, using various known techniques (§0030). By using the skull expansion monitor to measure the change in skull expansion corresponding to this known change in ICP, the system is calibrated, and thereby able to use skull expansion measurements to determine absolute ICP (§0035-0036).

The analyzer of the Henriquez reference is for detecting intersaccular aneurysms, which create “characteristic acoustic signals” (col. 1, line 14) in response to the pumping of the blood. Henriquez does confirm that the eye provides a “window” to the brain, unobstructed by bone, as also indicated in the background section of the present invention (page 2, lines 8-9). However, the addition of Henriquez presumably makes the Yost invention inoperable, since Yost measures skull expansion and requires that the sensors be in contact with the skull. While Henriquez does not expressly deny contact between the sensor and the bone around the eye socket, Henriquez emphasizes reliance upon the acoustic impedance of the soft tissue of the brain, the surrounding fluids, the eyeball, the eyelid and associated tissues, which approximates the acoustic impedance of water (col. 1, line 61, to col. 2, line 6). It is clear that Henriquez contemplates “a cupping structure for disposing an acoustic matching medium between the patient’s eye socket and the sensor” (col. 1, lines 59-61), and those skilled in the art would understand that contact with bone would defeat this objective of a matching acoustic impedance. Consequently, it is believed that Henriquez uses “eye socket” to refer to the opening for the eye rather than the bone portion. In any event, use of the rims of the goggles to provide support

by being in contact with bone is a separate and distinct function from the matching acoustic impedance required for the sensor itself.

Further, Yost operates by measuring distance between two points on the skull on opposite sides of the cranial cavity (see Yost, ¶0023: “pressure pads 26 and 28 are positioned at approximately diametrically opposed positions about skull 10”). In order to measure skull expansion by measuring distance, both endpoints have to be on the skull, and on opposite sides of the skull. Indeed, the endpoints must be at the same points used for calibration, otherwise the calibration is not valid, as would be understood by one skilled in the art..

It is believed, however, that the foregoing claim amendments clarifying that the sensors of the present invention are so adapted as not to come in contact with the skull – which is exactly contrary to the teaching of Yost – makes moot this ground of rejection, which is thereby overcome.

In the Office Action mailed prior to the interview the Examiner maintained rejection of claims 2, 4, 9 and 11 under 35 U.S.C. §103(a) as being unpatentable over Yost in view of Henriquez and further in view of U.S. Patent No. 5,919,144 to Bridger et al. (“Bridger”). The Yost/Henriquez combination is not an adequate reference, as explained above, and therefore this ground of rejection is also overcome. The Bridger reference discloses use of frequencies in the range of 100kHz (col. 2, line 20), but does not overcome the deficiencies of Yost and Henriquez regarding the other elements of the rejected claims. It is noted that Bridger discusses the use of a resonant frequency (col. 2, line 48), but takes the measurement on the forehead (col. 3, line 35), with consequent interference of the skull bone with the signal (as described in Henriquez), which Bridger seeks to overcome with signal processing (col. 3, lines 36-50).

In the Office Action mailed prior to the interview the Examiner maintained rejection of claims 7 and 14 under 35 U.S.C. §103(a) as being unpatentable over Yost in view of Henriquez and further in view of U.S. Patent No. 6,423,001 to Abreu. The

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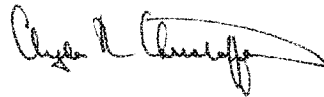
Yost/Henriquez combination is not an adequate reference, as explained above, and therefore this ground of rejection is also overcome.

In view of the foregoing, it is requested that the application be reconsidered, that claims 1-14 be allowed, and that the application be passed to issue.

In further emphasis upon the above underlined request for an interview should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: clyde@wcc-ip.com) to discuss any other changes deemed necessary.

If a further extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Sincerely,



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